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09/889,085	01/09/2002	Patricia Lynne Conway	28053/38258	6842

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/889,085

Applicant(s)

CONWAY ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 20-41 and 63-155 is/are pending in the application.
- 4a) Of the above claim(s) 20-40 and 63-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 41 and 76-153 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of claims***

New claims 77-153 are submitted [10/27/2003].

Claims 1-19 and 42-62 are cancelled by applicants [10/27/2003].

Claims 21-40 and 63-75 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter in the last office. Election was made without traverse [3/03/2003]. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **Claims 41 and 76-153 are under examination in the instant office action.**

Applicants' request to subject claims 41 and 76 to restriction requirement (response filed 10/27/2003, page 13) has been considered. However, claims 41 and 76 encompass the subject matter directed to a microbial product (Group I) as the canceled claims 1-19 and/or new claims 77-153. Thus, claims 41 and 76 are examined together with new claims 77-153.

### ***Claim Objections***

Claims 41 and 76 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because previous claim 20 has been withdrawn. Applicants are required to cancel the claims 41 and 76 or rewrite the claims 41 and 76 in independent form.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 41, 76, 77, 79, 81, 88, 90-105, 109-120, 124-135 and 139-150 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,143,845 [A].

Claims are directed to a microbial product comprising one component such as "harvested microbes" or grown/cultured microbes that have improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes. Some claims are further drawn to the use of microbes including representatives of the genera *Lactobacillus*, *Bifidobacterium*, *Clostridium*, *Bacillus*, etc. in the microbial products.

The cited patent is relied upon as explained in the last office action and repeated herein.

US 5,143,845 [A] discloses a microbial product comprising harvested or cultured microbes having improved characteristics or a microbial preparation comprising live symbiotic mixture of bacteria (see abstract). The microbial preparations are incorporated into a pharmaceutical product comprising potato starch (col. 2, lines 45-46 or col. 3, lines 16-25) and/or into other food or feed products suitable for delivery of the live probiotic microorganisms (col. 1, line 39-40) including fluid-based products (col. 7, line 17) and/or milk derivative or milk casein containing products (col. 5, line 52). The microbes were cultured and harvested before incorporation into the products (example 2) and, thus, they are "harvested" or cultured, activated and proliferated. The cited patent teaches that the resulting microbial preparations are capable to effectively proliferate (col. 4, lines 18), that they demonstrate satisfactory effects upon administration as related to maintenance and recovery in the digestive tract (col. 3, lines 65-68) and that they are characterized by heat stability, dry stability and drug stability (col. 2, lines 53-55). Thus, the activated microbial preparation of the cited patent are characterized by an

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increased survival/recovery rate and they are substantially unaffected by stresses within the meaning of the instant claims. The microbial products of the cited patent include representatives of the genera *Lactobacillus*, *Bifidobacterium*, *Clostridium*, *Bacillus* and others (col. 2, lines 34-44) as the microbial preparations of instant claims 96-99, 111-114, 126-129, and 141-144.

Therefore, the cited patent US 5,143,845 discloses identical composition comprising microbial preparations characterized by increased survival, viability and recovery as required for the claimed product. Thus, the cited patent US 5,143,845 anticipates the presently claimed invention.

Claims 41 and 76-153 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,050 [B] in the light of evidence by US 5,714,600 [C].

Claims are directed to a microbial product comprising one component such as "harvested microbes" or grown/cultured microbes that have improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of a second component such as resistant starch into the total microbial products, to the amounts of resistant starch in the total microbial products such as 0.1-90 % (w/) or about 10% (w/w). Some claims are further drawn to the use of various forms of resistant starch in the total products including resistant starches derived from maize, rice, barley, potatoes and resistant starches having amylose content at least 70 %, 80% or 90%. Some claims are further drawn to incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes. Some claims are further drawn to the use of microbes including representatives of the

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genera *Lactobacillus*, *Bifidobacterium*, *Clostridium*, *Bacillus*, *Saccharomyces*, *Clostridium*, etc. the microbial products.

US 6,060,050 [B] teaches a microbial preparation comprising harvested microbes with improved characteristics associated with survival/recovery in intestinal tract and it teaches incorporation of resistant starch into microbial preparations and/or into products with microbial preparations (col. 1, lines 55-65). The cited patent discloses amounts of resistant starch in the product and/or in the microbial preparations such as 2-20 % w/w (col. 2, lines 57-58) or 10% (col. 8, lines 15-25). The cited patent teaches the use of resistant starch RS1, RS2, RS3 or RS4 (col. 1, line 54) which is derived from maize, rice, barley, potatoes (col.4, lines 3-5) and to the use of maize resistant starch with amylose content of more than 50% or more than 80% (col. 3, lines 62-65). The phrase "more than" as related to the amylose content means "at least 90% " because the cited US 6,060,050 refers to the use of maize resistant starch disclosed in WO94/03049, which is now US 5,714,600, wherein the maize resistant starch having more than 80% of amylose include amylose contents of "at least 90% " (see US 5,714,600 col. 2, line 67). The resistant starch in the products of US 6,060,050 are also chemically or physically treated starches by chemical modification including esterification, acidification, etc. (col. 4, lines 15-21). The cited US 6,060,050 also teaches that microbes were cultured or grown on resistant starch containing media (col. 5, lines 31-36; col. 9, lines 50-55 and table 4) in order to select probiotic microorganisms that can grow on resistant starch (col. 2, lines 14-17) and to survive in the intestinal tract (col. 1, line 63-64). The microbes in the products of US 6,060,050 are characterized by a stress resistance including resistance to freezing and to freeze-drying (col. 2, line 50). The cited patent discloses to the use of various microorganisms including *Lactobacillus*,

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*Bifidobacterium*, *Clostridium*, *Bacillus*, *Saccharomyces*, *Clostridium* in the microbial products (col. 2, lines 20-25) and incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes (col. 4, lines 55-60). Thus, the cited patent US 6,060,050 anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 41 and 76-153 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,143,845 [A] taken with US 6,060,050 [B], Brown et al. [IDS-6] and US 5,714,600 [C].

Claims as explained above.

US 5,143,845 is relied upon as explained above for the disclosure of microbial products characterized by increased survival and recovery. US 5,143,845 is lacking particular disclosure about the use of resistant starch in the total product.

However, US 6,060,050 [B] teaches microbial products comprising microbes and various forms resistant starch.

Further, the reference by Brown et al. [IDS-6] is relied upon for the teaching directed to beneficial properties of resistant starch and to a clear suggestion to incorporate resistant starches into microbial preparations/products for improving robustness and viability of probiotics in gastrointestinal tract and in the food products (table 2). It is also teaches that the high amylose

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maize resistant starch is particularly beneficial for lactic acid bacteria because it enhances bacterial survival and stress resistance (page 607, col. 1).

The cited patent US 5,714,600 [C] is relied upon to demonstrate that physically and/or chemically modified resistant starch (col.7, lines 13-15) including maize starch having high amylose contents of at least 40-90% (col.2, lines 63-67) are available in the prior art and they have been suggested for various compositions including foods and other industrial products (col. 1, line 24).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify compositions of US 5,143,845 [A] by incorporation of maize resistant starch of US 6,060,050 [B] or of US 5,714,600 with a reasonable expectation of success in increasing survival and recovery of microbial preparations in various products because benefits of incorporations of resistant starch into probiotic compositions are known as adequately demonstrated by Brown et al. [IDS-6]. One of skill in the art would have been motivated to use high amylose maize resistant starch in microbial preparations/products for the expected benefits related to the improved viability and to stress resistance of probiotic cultures {Brown et al. [IDS-6]}. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.



### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41 and 76-153 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,221,350 [D].

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to microbial probiotic products comprising microorganisms and resistant starch.

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Claims of US 6,221,350 appear to be narrower and they require 3 components in the product including microorganisms, resistant starch and oligosaccharide. Some of the claims of the instant application are broader and they are drawn to generic microbial products, for example: claims 41, 77, 79, 81, or 88. However, some of the claims of the instant applications are drawn to products comprising both microorganisms and resistant starch, for example: claims 78, 80, 82-87, 89, 106-108, 121-12, 136-138 and 151-153. The microorganisms in the compositions of the instant application and of the cited patent are identical, for example: see patented claims 3-6 and see instant 96-99, 111-114, 126-129 and 141-144. The resistant starch in the compositions of the instant application and of the cited patent is identical, for example: see patented claims 9-12 and instant claims 83-87. Although the claims of the instant application are not clearly directed to the use of oligosaccharides, they encompass the use of food products including confectionary, biscuits, desserts or flavored drinks that do not exclude the use of oligosaccharides or fructo-oligosaccharides and, therefore, are reasonably expected to comprises at least some amounts of oligosaccharides or fructo-oligosaccharides.

Accordingly, the claimed compositions are obvious variants. Thus, the inventions as claimed are co-extensive.

### ***Response to Arguments***

Applicants' arguments filed 10/27/2003 have been fully considered but they are not persuasive.

With regard to US 5,143,845 {Masuda et al.} applicants argue that the microbes in the product the cited patent are not harvested after culturing on a resistant starch (response page 15). However, even though the presently claimed product is defined by a process of making, the

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patentability of a product does not depend on its method of production. MPEP 2113. In the instant claims, the final product or final microbial preparation is said to be relatively better than a starting microbial preparation with respect to microbial survival and recovery. However, neither starting nor end products are particular microbial strains that are available, reliable and characterized by some particular rates of survival or recovery. Thus, in view of a relative characterization that is defined by the structure of the instant claims, the claimed microbial product *per se* has only one final physical or measurable feature such as viability or capability to survive/recover. Therefore, the cited microbial product that is characterized as having increased capability to proliferate and to survive, that is stress resistant, that is capable to utilize generic starch and that is taught as suitable for pharmaceutical and food products is within the scope of the claimed product. Regardless the fact that different forms of resistant starches are encompassed by the process steps of growing and/or adapting microbes, the end microbial products are no more than viable microbial compositions capable to survive and to recover.

But the applicants' argument that the cited patent US 5,143,845 {Masuda et al.} does not define a generic potato starch as a resistant starch (response page 17, par. 3) has been found persuasive with respect to the claims drawn to a product comprising two components such as viable microbes and resistant starch.

With regard to the cited patent US 6,060,050 {Brown et al.} applicants argue that the microbes in the product the cited patent are not harvested after culturing on a resistant starch but after culturing on a conventional medium (response page 16). This is not found true because the cited patent teaches microbial preparations grown on resistant starch, for example: see col. 5, lines 32-36. Moreover, the particular disclosure that is referred by applicants (col.7, line 38),

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teaches the use of "conventional means" but not a conventional medium as presently argued. Further, even though the cited patent does not clearly disclose active step of comparing starting and end microbial products, the final microbial product as disclosed by the cited patent is clearly said to comprise two components including viable microbes and resistant starch as required for the presently claimed product. Thus, the disclosed product is within the scope of the claimed product.

With regard to the reference by Brown et al. [IDS-6] and US 5,714,600 [C] applicants' arguments are directed to a method of making product but not to a characterization of a product. The cited references adequately demonstrate suggestion and motivation to combine resistant starch and viable microbial preparations as explained above and they also demonstrate availability of different forms of resistant starches.

With regard to the obviousness-type double patenting rejection applicants' arguments are not found persuasive because they are directed to the differences in the methods of administration and methods of making but not to the structural differences between end products or distinctions between claimed compositions that would affect functional properties of the final products as claimed. The pending claims are drawn to a product not to the methods of making and using that are argued.

Furthermore, the composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

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No claims are allowed.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351 till January 15, 2004 or (571) 271-0914 after January 15, 2004. The examiner can normally be reached on 9.30 am - 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743 till January 15, 2004 or on (571) 272-0926 after January 15, 2004.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova



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VERA AFREMOVA

January 13, 2004.

PATENT EXAMINER